

Attorney Docket No.: KUZ-0022  
Inventors: Ito et al.  
Serial No.: 10/527,710  
Filing Date: April 22, 2005  
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#### REMARKS

Claims 1-10 are pending in the instant application. Claims 1-10 have been rejected. Claims 8 and 9 have been objected to. Claim 8 has been amended to be independent. Support for these amendments is provided in claim 1 and in teachings in the specification at pages 7-9. No new matter is added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Claim Objection**

Claim 8 and 9 have been objected to. Specifically, claim 1 recites "consisting essentially of" while claim 8, which depends from claim 1, recites "further comprising".

Accordingly, in an earnest effort to overcome this objection, claim 8 has been amended to be independent. Support for this amendment is provided in claim 1 and in teachings of the specification at pages 7-9.

Withdrawal of this objection is respectfully requested.

#### **II. Rejection of Claims 1-10 under 35 U.S.C. 112, first paragraph**

Claims 1-10 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner suggests that the

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specification does not provide a clear indication of what the basic and novel characteristics are, and therefore the term "consisting essentially of" will be treated as being equivalent to "comprising".

Applicants respectfully disagree.

Contrary to the Examiner's suggestion, the specification provides a clear indication of the elements in the pressure sensitive adhesive layer following the phrase "consisting essentially of" in claim 1 being basic and novel characteristics of the long-term drug efficacy of the present invention.

Applicants respectfully direct the Examiner to page 5, lines 12-14, of the specification, wherein it is taught that "[a] pharmacologically active substance in the adhesive patch for percutaneous fentanyl administration of the invention is fentanyl itself and does not contain a salt thereof." This teaching addresses the Examiner's query at page 3, line 1 of the June 11, 2008 Office Action.

Applicants disagree with the Examiner that the transitional phrase should be "consisting of" if the compound is limited to fentanyl, since the transitional phrase relates to the pressure-sensitive adhesive layer, not simply the compound.

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Applicants also respectfully direct the Examiner to page 1-2 of the specification wherein the disadvantages of conventional fentanyl adhesive patches containing a drug salt such as disclosed in JP, A, 10-45570 (which corresponds to U.S. Patent 6,139,866 of Chono et al.) are described. These include not being suitable for maintaining long-term efficacy.

Further, Applicants respectfully direct the Examiner to page 6, lines 4-6 of the specification wherein it is stated that "[i]n addition, the pressure-sensitive layer of the adhesive patch of the invention comprises a pressure sensitive adhesive base and a tackifier"; page 6, line 24 through page 7, line 3, wherein it is taught that by mixing the pressure-sensitive adhesive base in the claimed proportions "long-term administration, the objective of the invention, can be achieved"; and page 7, beginning at line 4, which teaches the tackifier agent to be "another indispensable ingredient of the pressure sensitive adhesive."

Accordingly, the written description makes clear that fentanyl as an active ingredient, a pressure-sensitive adhesive base at the particular claimed polymer ratio, and a tackifier resin are the basic and novel elements of the

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pressure-sensitive adhesive layer of the adhesive patch for maintaining a long-term drug efficacy as claimed.

Withdrawal of this rejection is respectfully requested.

**III. Rejection of Claims 1-10 under 35 U.S.C. 112, second paragraph**

Claims 1-10 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has requested clarification of the basic and novel characteristics of claim 1 which recites "consisting essentially of".

As outlined in Section II, supra, the specification provides a clear indication of the elements in the pressure sensitive adhesive layer following the phrase "consisting essentially of" in claim 1 being basic and novel characteristics of the long-term efficacy of the present invention. Specifically, at page 5, lines 12-14, of the specification, it is taught that "[a] pharmacologically active substance in the adhesive patch for percutaneous fentanyl administration of the invention is fentanyl itself and does not contain a salt thereof." At page 6, lines 4-6 of the specification it is stated that "[i]n addition, the

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pressure-sensitive layer of the adhesive patch of the invention comprises a pressure sensitive adhesive base and a tackifier". Further, at page 6, line 24 through page 7, line 3, it is taught that by mixing the pressure-sensitive adhesive base in the claimed proportions "long-term administration, the objective of the invention, can be achieved". In addition, at page 7, beginning at line 4, of the specification, it is taught that the tackifier agent is "another indispensable ingredient of the pressure sensitive adhesive."

Accordingly, the specification makes clear that fentanyl as an active ingredient, a pressure-sensitive adhesive base at the particular claimed polymer ratio, and a tackifier resin are the basic and novel elements of the pressure-sensitive adhesive layer of the adhesive patch for maintaining a long-term drug efficacy as claimed.

MPEP 2173.02 is clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The contents of the particular application disclosure;

(B) The teachings of the prior art; and

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(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

The claims of the instant application are clearly definite when analyzed in light of teachings of the specification as required by MPEP 2173.02.

Withdrawal of this rejection is respectfully requested.

#### **IV. Rejection of Claims 1-10 under 35 U.S.C. 103(a)**

The rejection of claims 1-3 and 7-9 under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866) in view of Tsuruda et al. (CA 2 424 579) has been maintained.

The rejection of claim 4 under 35 U.S.C 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Urquhart et al. (U.S. Patent 4,031,894) has been maintained.

The rejection of claim 5 under 35 U.S.C 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Scholz et al. (U.S. Patent 5,750,136) has been maintained.

The rejection of claim 6 under 35 U.S.C 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and

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further in view of Higo et al. (U.S. Patent 5,866,157) has been maintained.

The rejection of claim 10 under 35 U.S.C 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al. and further in view of Zaffaroni (U.S. Patent 3,598,122) and further in view of Kochinke (U.S. Patent 5,350,581) has been maintained.

Applicants respectfully traverse these rejections.

Arguments presented in Applicants' reply filed March 11, 2008 were deemed not persuasive as the Examiner suggests that the specification does not indicate the basic and novel characteristics. Thus, the Examiner has treated the term "consisting essentially of" as being equivalent to comprising.

As discussed in detail in Sections II and III, supra, contrary to the Examiner's suggestion, the specification makes clear that fentanyl as an active ingredient, a pressure-sensitive adhesive base at the particular claimed polymer ratio, and a tackifier resin are the basic and novel elements of the pressure-sensitive adhesive layer of the adhesive patch for maintaining a long-term drug efficacy as claimed. Accordingly, the transitional phrase "consisting essentially of" should be interpreted as limiting the scope

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of the claim to the specified materials and those that do not materially affect the basic and novel characteristics of the claimed invention. See MPEP 2111.03.

None of the cited references alone, or in combination, disclose, suggest, or predict all of the limitations of these claims.

Instead, Chono et al., which corresponds to Patent Document 2, JP, A, 10-45570, and is distinguished from the present invention at pages 1 and 2 of the instant patent application, employs an ion-pair type adhesive patch. Accordingly, even Example 6 of Chono et al., which is the only example of 15 to use fentanyl instead of fentanyl citrate, also employs sodium acetate. Such a patch comprising fentanyl and sodium acetate cannot maintain the claimed property of the instant invention of fentanyl in free form. In addition, both the content of polyisobutylene (PIB) and the proportion of PIB to styrene-isobutylene-styrene (SIS) block copolymer in all of the exemplary compositions of Chono et al. are outside of the limitations specified in the instant claims following the transitional phrase "consisting essentially of".

Secondary references fail to remedy the deficiencies in the primary reference of Chono et al. as these references



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also neither teach or suggest use of a non-salt form of fentanyl, nor its combination with the specified ratio of polymers in the pressure-sensitive adhesive base as claimed.

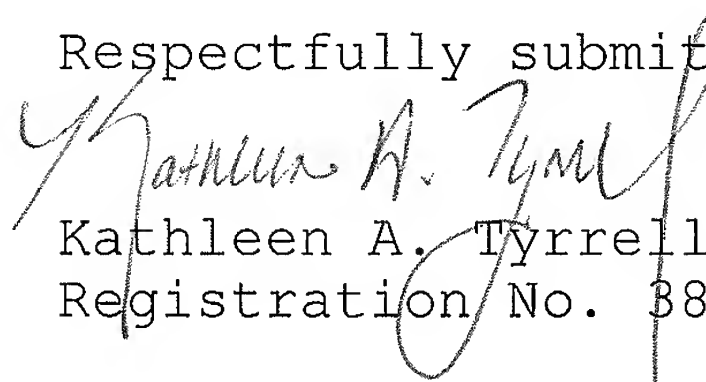
Thus, since the cited combinations of references fail to teach or suggest all the limitations of claim 1 and claim 8, they cannot render obvious the invention of claim 1 or 8, nor claims dependent therefrom. See MPEP 2143 and MPEP 2143.03.

Withdrawal of these rejections under 35 U.S.C. 103(a) is therefore respectfully requested.

#### **V. Conclusion**

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

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Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515